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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,695	02/04/2004	Paul D. Hanke	040049	4373

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EXAMINER	
KIM, ALEXANDER D	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,695	HANKE ET AL.	
	Examiner	Art Unit	
	Alexander D. Kim	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Claims 1-32 are pending in the instant case.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to an isolated peptide of SEQ ID No. 2, classified in class 435, subclass 194.

II. Claims 2-16, drawn to a method of producing lysine comprising culturing the host cells, classified in class 435, subclass 115.

III. Claims 17-18, drawn to an isolated polypeptide related to SEQ ID No. 19, classified in class 530, subclass 350.

IV. Claims 19-24, drawn to an isolated nucleic acid (including SEQ ID No. 18), a vector, a host cell and a method for selecting a transformant, encoding protein related to SEQ ID No. 19, classified in class 536, subclass 23.1.

V. Claims 25-26, drawn to an isolated protein related to SEQ ID No. 21, classified in class 530, subclass 350.

VI. Claims 27-32, drawn to an isolated nucleic acid (including SEQ ID No. 20), a vector, a host cell and a method for selecting a transformant, encoding protein related to SEQ ID No. 21, classified in class 536, subclass 23.2.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I, III and V are related to each other by the virtue of proteins involved in the biosynthesis of lysine in *Corynebacterium* species. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each protein of Group I, III and V are mutually exclusive to each other and are not obvious variants to each other because each protein has distinct amino acid sequences identified by a distinct SEQ ID No. Therefore, each protein requires a separate search against the database because of distinct protein sequences. Three proteins have different functions and effects from each other inside the bacterium because they catalyze distinct chemical reactions utilizing distinct substrates.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Groups I, III, V are related to Group II by the virtue the micro-organism used in the method of Group II contains genes encoding for proteins of Group I, III, V. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e.,

are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the micro organism used in the method of Group II is made up of many different materials and composed into very highly ordered structures for the cellular metabolic pathway but Groups I, III, V is made from amino acids and the complexity of structural order is nowhere close to a bacteria. Thus Groups I, III, V and Group II are mutually exclusive and not obvious variants. Proteins of Group I, III, V can not be used together with Group II because of distinct functions; the micro-organism used by method of Group II consist of many chemical processes, replicate itself and useful for amplifying a gene whereas each enzymes of Groups I, III, V catalyze a specific chemical reaction.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I and Group IV, VI are not related products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, genes of Group IV, VI encode protein ORF2 (truncated) and LysA

(truncated), respectively, which are distinct from the protein of Group I. A nucleic acid's structure is comprised of linear, contiguous nucleotides while a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the nucleic acid's function is to encode a protein while a protein's function is variable, and in this case, biosynthetic enzyme for the production of lysine. Therefore, Group I is patentably distinct from Groups IV, VI.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Proteins of Group III, V are related to nucleic acids of Group IV, VI, respectively, by virtue of the fact that proteins of Group III, V are encoded by nucleic acids of Group IV, VI, respectively. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the nucleic acid molecule has utility for the recombinant production of the protein in a host cell. Although the nucleic acid and the protein are related, they are distinct inventions because they are wholly different in

structure and function. A nucleic acid's structure is comprised of linear, contiguous nucleotides while a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure. Therefore, proteins of Group III, V are mutually exclusive and are not obvious variants from Group IV, VI as described above. Because the nucleic acid's function is to encode a protein while a protein's function is variable, proteins of Group I, III, V catalyze chemical reactions in the instant case, the protein of Group I cannot be used together with nucleic acids of Group IV and VI. Additionally, the nucleic acid sequences must be searched in distinct nucleic acid sequence commercial databases.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group II and Group IV, VI are related by the virtue of nucleic acids of Group IV, VI and a method of Group II using microorganism containing nucleic acids of Group IV, VI. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP §

806.05(j). In the instant case, the *Corynebacterium* is made up of many different materials and composed into very highly ordered structures for the cellular metabolic pathway but the nucleic acid have a molecule whose structural order is nowhere close to a bacteria. The bacterium has very dynamic chemical processes, whereas a nucleic acid changes very little over the time. The bacteria can replicate itself with given nutrients whereas the nucleic acid cannot replicate itself without help of enzymes. Group II and Group IV, VI are mutually exclusive and not obvious variants as described above. Thus the Group II and Group IV, VI are two distinct products with distinct structures and functions.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group IV and Group VI are directed to related product by the virtue of the fact that all genes encode proteins that are involved in lysine biosynthetic pathway. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the

instant case, nucleic acids of Group IV is distinct from nucleic acids of Group VI because of their distinct structure (different SEQ ID NOs) and distinct functions (encoding proteins that function differently). Thus, Group IV is patentably distinct from Groups VI.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alexander Kim
13 March 2006

KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER